

OLLERENSHAW et al  
Serial No.: 09/769,769  
July 22, 2004

REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested.

Claims 14 and 47-49 stand rejected under 35 USC 102(b) as allegedly being anticipated by Bruchman et al. The rejection is traversed.

Claim 14 is drawn to a tissue graft product from an ureter that is subjected to decellularization and nuclease treatment.

The Examiner contends that Bruchman et al discloses "a method" for preparing a tissue graft from bovine ureter as claimed. The Examiner further contends that Bruchman et al discloses "a tissue graft product" that is subject to decellularization and nuclease treatment.

Bruchman et al relates to vascular prostheses derived from vessels. This is in contrast to the tissue graft of the present invention which derives from a ureter. Given this fundamental difference in starting material, no basis for the rejection is seen.

The Examiner refers to the method used by Bruchman et al at columns 7, 8 and 9. Any similarity in these steps and those used to define the claimed product in no way negates the difference in the starting material used.

OLLERENSHAW et al  
Serial No.: 09/769,769  
July 22, 2004

Indeed, Bruchman et al underscores the uniqueness of the disclosed vessels as starting material. In column 1, lines 19-33 (a portion of Bruchman et al previously relied upon by the Examiner), it is stated that:

Attempts have also been made to replace arteries with tissues of nonvascular origin, including autologous or xenogeneic fibrous tissue tubes, bovine ureter, and grafts made from small bowel and pericardium. However, like the above grafts from vascular sources, these nonvascular biological grafts have provided only very limited success.

Further, at column 6, lines 1-4, Bruchman et al states:

The improved thromboresistance of the present invention is believed to result from a naturally occurring mechanism present in arteries that resides in the extracellular matrix layer found beneath the endothelium.

(Underlining added.)

In rejecting the claims as anticipated, the Examiner appears to be contending that, once decellularized and nuclease treated, there is no distinction between an artery and a ureter. However, given the teachings of the citation itself (including those portions referenced above), absolutely no basis is seen for such an assertion.

OLLERENSHAW et al  
Serial No.: 09/769,769  
July 22, 2004

In view of the fact that the product of the reference derives from a tissue (artery) fundamentally different in structure and purpose from that of the instant invention (ureter), withdrawal of the rejection is submitted to be in order and same is requested.

Claims 14 and 47-49 stand rejected under 35 USC 102(e) as anticipated by Tanagho et al. The rejection is traversed.

In rejecting the claims over Tanagho et al, the Examiner directs attention to column 2, lines 16-60 and column 3, lines 21-25 (which defines "enzymatic digestion").

Lines 16-22 of column 2 of the citation make reference to an acellular matrix graft isolated from, for example, smooth muscle tissue such as ureter. Lines 23-39 of column 2 describe the preparation of a bladder acellular matrix graft from an excised bladder cap. Lines 40-46 of column 2 describe methods of restoring muscle function by replacing the damaged or diseased tissue with an organ specific acellular matrix graft. Lines 47-54 of column 2 describe a method of restoring bladder function by replacing the damaged portion with a bladder acellular matrix. Lines 55-60 of column 2 describe a method of promoting regrowth and

OLLERENSHAW et al  
Serial No.: 09/769,769  
July 22, 2004

healing of a damaged/diseased muscle tissue by replacing that tissue with a matrix graft from an organ specific tissue.

In the prior Action, the Examiner relied on column 2, lines 16-22 of Tanago et al. It is not clear why the Examiner now relies on portions of the document that relate specifically to bladder - clarification is requested so that Applicants can ensure that they are fully responsive to the Examiner's concerns.

It was pointed out in the prior Amendment that Tanagho et al refers throughout to the use of chemical and enzyme agents to "initiate" lysis and release cellular components and to "initiate" removal of cells from the matrix (see, for example, column 2, lines 33-35, column 5, line 49 to column 6, line 12, and Example 1). Tanagho teaches that such treatment results in an "intermediate matrix" that is then further treated to solubilize and remove remaining cell membranes and intracellular lipids. At the top of column 6, it is taught that typically chemical methods are used to effect this further treatment (preferably, a sodium desoxycholate solution containing sodium azide).

(Column 3, lines 21-25, to which the Examiner now refers in no way negates the foregoing teachings.)

OLLERENSHAW et al  
Serial No.: 09/769,769  
July 22, 2004

The complex approach used by Tanagho et al is markedly different from the simple, gentle process used to produce the graft of the present invention. Absolutely no basis is seen for the Examiner's assertion that the product that results from Tanagho et al's multiple chemical treatments (in addition to enzyme treatment) is the same as the product that results from Applicants' process which consists essentially of effecting lysis using an osmotic effect, nuclease treating the resulting tissue matrix and then washing out debris.

In maintaining the rejection over Tanago et al, the Examiner contends that the transitional phrase "consisting essentially of", used in the instant claims, has been construed as "comprising". While the Examiner refers to MPEP 2111.03 as providing authority for such a construction, nothing is found there that would support the Examiner's position

It is now well settled that the transitional term "comprising", is synonymous with "including" and is inclusive and thus does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 42 USPQ2d 1608 (Fed. Cir. 1997). By contrast, the transitional phrase "consisting essentially

OLLERENSHAW et al  
Serial No.: 09/769,769  
July 22, 2004

of", used in the instant claims, limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. In re Herz, 190 USPQ 461, 463 (CCPA 1976).

The MPEP section cited by the Examiner indicates that:

For the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ...

... If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lafarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)

Applicants do indeed contend that the multiple chemical treatments of Tanagho et al, which are excluded from the instant claims, would materially change the characteristics of the invention.

OLLERENSHAW et al  
Serial No.: 09/769,769  
July 22, 2004

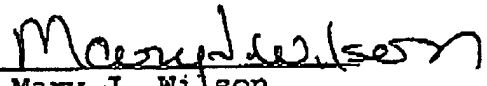
First, Tanagho et al makes the point that the chemical methods used in the above-referenced "further treatment" of the "intermediate matrix" are not without effect.

Furthermore, as pointed out in the prior response, Applicants have found with other tissues that, in fact, the claimed approach of effecting decellularization results in a product that is less antigenic than a product obtained using "chemical poisoning", as taught by the citation. This reduction in antigenicity is clearly advantageous and is a manifestation of structural differences between the products of the two processes.

In view of the above, reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,  
NIXON & VANDERHYE, P.C.

By   
Mary J. Wilson  
Reg. No. 32,955

MJW:tat

1100 North Glebe Road  
8<sup>th</sup> Floor  
Arlington, Virginia 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100